REMARKS

Applicant thanks the examiner for acknowledging the submitted Information Disclosure Statement.

Claim Disposition

Claims 30-55 are pending in the application. Claims 30, 31, 35, and 53 are amended without disclaimer or prejudice and applicants hereby reserve the right to file continuing applications or take any other such appropriate measure to prosecute the subject matter deemed cancelled by amendment. Claims 56-61 are new. Claims 30-61 will be pending in the application upon entry of this amendment.

Support for Claim Amendments and New Claims

The claim amendments and the new claims presented in this submission are supported by the specification and the claims as originally filed. No new matter is entered by way of this submission. Claim 30 is amended as set forth above to expressly recite the phrase "treatment and/or amelioration of symptoms"; this amendment supported for example, by page 1, line 9 of the specification. Claims 30 is amended to expressly recite the phrases "...includes less than 10^5 bacteria per dosage..." (supported for example, by page 6, line 18 of the specification); "...the medicament comprises at least 75 percent by weight of said saccharide..." (supported for example, by page 6, lines 8-10 of the specification); and "...the medicament is a gel or suspension comprising at least 40% by weight of said saccharide..." (supported for example, by page 7, lines 21 and 24 of the spcification). Claim 53 is amended to expressly recite the phrases "...including less than 10^5 bacteria per dosage..."; "...said saccharide constitutes at least 75 percent by weight of said composition..."; and "...the pharmaceutical composition is a gel or suspension and said saccharide constitutes at least 40 % by weight of said pharmaceutical composition". These amendments to claim 53 are respectively supported as stated in this paragraph with regards to claim 30.

Support for new claims 59-61 is found for example, on page 6, lines 29-31 of the specification.

The Claim Rejections Under 35 USC §112, Second Paragraph, Should be Withdrawn

Claims 30, 31 and 35 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness.

Claim 30 was rejected for reciting the phrase "administering an effective amount of a medicament". Claim 30 is amended as set forth above to recite "...administering to an individual in need an effective amount...".

Claim 31 was rejected for reciting the phrase "such as". Claim 31 is amended as set forth above to delete this phrase.

Claim 35 was rejected for reciting the phrase "preferably selected from lactose". Claim 35 is amended as set forth above to delete this phrase.

Accordingly as each claim rejection under 35 U.S.C. §112, second paragraph, is obviated by amendment, applicant respectfully requests that this rejection of the claims under consideration be withdrawn.

The Claim Rejections Under 35 USC §112, First Paragraph, Should be Withdrawn

Independent claim 30 and claims 31-52 dependent thereon, are rejected under 35 U.S.C. § 112, first paragraph, allegedly for lacking sufficient written description; although, the Office Action seems to conclude that the claims lack enablement. See for example, page 3, line 13; and page 5, lines 7-18 of the Office Action. This rejection of the claims under consideration is respectfully traversed. As a first point, applicant respectfully submits that this rejection of the claims under 35 USC §112, first Paragraph, is improper, as the Office Action does not clearly establish whether this rejection of the claims under consideration is a "written description" rejection, or an "enablement" rejection, or both. In light of this lack of clarity, applicant requests that the rejection be withdrawn or clarified.

Nevertheless, to facilitate prosecution, independent claim 30 is amended as set forth above, to delete the recitation of the phrase "...and/or prophylaxis..."; the subject matter now presented in new claim 58.

While pages 3-5 of the Office Action, indicate that this rejection of the claims is primarily directed to the prophylaxis aspect of the claims under consideration, in regards to "modes of treatment", lines 10-13 of the Office Action provides:

> "Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success."

Applicants respectfully disagree. The specification is replete with the requisite disclosure for the purposes of 35 U.S.C. 112, first paragraph. For example, applicant refers to lines 18 to 25, page 2 of the specification (diagnosis criteria); page 6 describing, and Examples 1-8 illustratively describing the makeup of the medicament utilized in the claims under consideration; and Example 9 not only illustrating relevant treatment *in vivo* in a patient, but also clearly showing evidence of amelioration of the symptoms.

In light of the above, applicant respectfully submits that this rejection of claims 30-52 should be withdrawn.

Furthermore, as indicated above, new claim 58 is now directed to "A method for prophylaxis of bacterial vaginosis...". Applicants respectfully submit that the present rejection under 35 U.S.C. § 112, first paragraph, should not be extended to the new claims. In light of the description provided in the specification, including lines 10-25, page 2 of the specification; page 6 describing, and Examples 1-8 illustrating the makeup of the medicament utilized in the claims under consideration; and Example 9 illustrating relevant treatment *in vivo* in a patient, Applicant submits that it would be within the skill level of the ordinarily skilled artisan, to carry out the claimed prophylaxis in an individual that does not fully meet the diagnosis criteria for bacterial vaginosis.

Even furthermore, with respect to the statements in the Office Action directed to the proposition that a single cause for bacterial vaginosis, or for its relapses is unknown, Applicants respectfully direct the examiner to the bridging paragraph of pages 1 and 2 of the specification, which paragraph clearly describes causal relationships between the imbalance in the normal vaginal flora and reductions in the pH-lowering lactobacilli, and rises in virulent and anaerobic bacteria in the context of bacterial vaginosis. However, Applicant respectfully submits that existence of a single art-recognized cause for a particular disease or disorder is not a requirement for satisfying enablement or written description under 35 U.S.C. 112, first paragraph, for a method of treating or for a method of prophylaxis of the disease. As indicated above, the claimed invention is directed to the described methods comprising administering a specified composition as claimed, and the specification clearly describes the composition, methods of making and administering it, as well as illustrating eight ways of making the composition, as well as providing a working example in a human patient clearly showing evidence of amelioration of symptoms.

In light of all of the above, applicants respectfully request that this rejection of the claims under consideration be withdrawn and not extended to the new claims.

The Claim Rejections Under 35 USC §102 Should be Withdrawn

The Office Action states that Claims 53-55 were rejected under 35 U.S.C. §102(b) as anticipated by Woitun et al. (DE 1959402 A) (Abstract only).

As set forth and explained above, claim 53 includes recitation in the alternative, of the phrases "...said saccharide constitutes at least 75 percent by weight of said composition..."; and "...the pharmaceutical composition is a gel or suspension and said saccharide constitutes at least 40 % by weight of said pharmaceutical composition", and thus a composition of claims 53-55 is limited by these recitations as set forth in the claim 53. The Woitun et al. reference does not mention any composition that includes one or more of these limitations. Accordingly, the Woitun et al. does not anticipate the present claims as amended, and applicant respectfully requests the withdrawal of this rejection of claims 53-55.

The Claim Rejections Under 35 USC §102/103 Should be Withdrawn

The Office Action states that claims 30-43 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ozmen et al. (Turkish Journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only).

Ozmen et al. refers to a method of treatment comprising administration of metronidazole alone or in combination with a Estriol composition (Gynoflor) further comprising at least $10^7 - 7 \times 10^8$ viable micro-organisms and 600 mg lactose (Page 172, 1st column, middle section). As set forth and explained above, claim 30 includes recitation "...includes less than 10^5 bacteria per dosage...", and thus a method of claims 30-43 is limited by this recitation as set forth in the claim 30. As the methods referred to in the Ozmen et al. reference do not include this limitation, the Ozmen et al. reference clearly does not anticipate present claims 30-43 as amended.

Furthermore, while the active component according to Ozmen is metronidazole, which is also mentioned in the application as filed (page 3, line 12), in the Ozmen et al. reference, lactose is provided as a substrate for the accompanying lactobacilli included in the Estriol composition Gynoflor. The lactose and lactobacilli are thus a functional unit. Therefore, it would not be obvious to one of ordinary skill in the art to omit or reduce either of the ingredients lactose or lactobacilli. Based on Ozmen, there would be no expectation of success by employing saccharide as active agent for treatment of vaginosis.

Furthermore, as the claims are compositionally limited to the specific content of the bacteria mentioned above, the ordinarily skilled artisan could not even envision the compositions employed in the present inventive methods, let alone modifying the methods referred to by Ozmen et al. and arriving at the claimed methods with a reasonable expectation of success.

In light of all of the above, applicant submits that claims 30-43 are neither anticipated nor obvious in view of the Ozmen et al. reference. Accordingly, applicant respectfully requests the withdrawal of this rejection of claims 30-43.

The Claim Rejections Under 35 USC §103 Should be Withdrawn

The Office Action states that Claims 44-48, and 51-52 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al. (Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only).

As mentioned above, Ozmen et al. refers to a method of treatment comprising administration of metronidazole alone or in combination with a Estriol composition (Gynoflor) further comprising at least $10^7 - 7 \times 10^8$ viable micro-organisms and 600 mg lactose (Page 172, 1st column, middle section). As set forth and explained above, claim 30 includes recitation "...includes less than 10^5 bacteria per dosage...", and thus a method of claims 30-52 is limited by this recitation. While the active component according to Ozmen is metronidazole, which is also mentioned in the application as filed (page 3, line 12), in the Ozmen et al. reference, lactose is provided as a substrate for the accompanying lactobacilli included in the Estriol composition Gynoflor. The lactose and lactobacilli are thus a functional unit. Therefore, it would not be obvious to one of ordinary skill in the art to omit or reduce either of the ingredients lactose or lactobacilli. Based on Ozmen, there would be no expectation of success by employing saccharide as active agent for treatment of vaginosis. Furthermore, as the claims are compositionally limited to the specific content of the bacteria mentioned above, the ordinarily skilled artisan could not even envision the compositions employed in the present inventive methods, let alone modifying the methods referred to by Ozmen et al. and arriving at the claimed methods with a reasonable expectation of success.

Claims 49-50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al. (Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only) in combination with Lin et al. (US 2003/0017207 A1). Lin et al. refer to use of anti-fungal agents; however, Lin et al. do not provide any motivation to use saccharide compositions with less than 10^5 bacterial per dosage. Put another way, the deficiency of the primary reference of Ozmen et al. with respect to the specific bacterial content of the claimed invention under consideration, is not removed by Lin et al. Therefore, further in view of the remarks above, claims 49-50 are non-

obvious over Ozmen et al. alone, or in view of Lin. et al. Accordingly, applicant respectfully requests the withdrawal of this rejection of claims 49-50.

In view of the above amendment, applicant believes the pending application is in condition for allowance, and such allowance is respectfully solicited.

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Respectfully submitted,

By _____

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